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| The purpose of this worksheet is to provide support for investigators conducting an emergency use of a test article in a life threatening situation and Designated Reviewers reviewing an emergency use of a test article in a life threatening situation. This worksheet is to be used when overseeing emergency use of a test article in a life-threatening situation. It does not need to be completed or retained. |
| Emergency Use of a Drug or Biologic |
| 1. Exemption Criteria for Emergency Use of a Drug or Biologic (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a disease or condition that is (was) either:[ ]  Life-threatening meaning diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. [ ]  Severely debilitating meaning diseases or conditions that cause major irreversible morbidity. |
| [ ]  Yes [ ]  No | The situation necessitates (necessitated) the use of the investigational article: |
| [ ]  Yes [ ]  No | No standard acceptable treatment is (was) available. |
| [ ]  Yes [ ]  No | There is (was) NOT sufficient time to obtain IRB approval. |
| [ ]  Yes [ ]  No | The emergency use will be (was) reported to the IRB within 5 working days. |
| [ ]  Yes [ ]  No | Any subsequent use of the investigational product at the institution will have prospective IRB review and approval. |
| [ ]  Yes [ ]  No  | The FDA has (had) issued an IND. |
| [ ]  Yes [ ]  No | The use is (was) **NOT** subject to DHHS regulation (See **WORKSHEET: Human Research Determination (HRP-309)**) |
| **One of Sections 2, 3, or 4 must be met** |
| 1. Consent Criteria (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | Informed consent will be (was) sought from the patient or the patient’s legally authorized representative, in accordance with and to the extent required by 21 CFR §50. See WORKSHEET: Criteria for Approval and Other Considerations (HRP-311) |
| [ ]  Yes [ ]  No | Informed consent will be (was) documented, in accordance with and to the extent required by 21 CFR §50.27. See WORKSHEET: Criteria for Approval and Other Considerations (HRP-311) |
| 1. Exception Criteria with Prospective Confirmation by an Independent Physician (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  Yes [ ]  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. |
| [ ]  Yes [ ]  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. |
| [ ]  Yes [ ]  No | Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing that the above items are (were) true. |
| 1. Exception Criteria with Retrospective Confirmation by an Independent Physician (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  Yes [ ]  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. |
| [ ]  Yes [ ]  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. |
| [ ]  Yes [ ]  No | Before the use of the test article a physician who is (was) not otherwise participating in the clinical investigation was unable to certify in writing that the above items are true. |
| [ ]  Yes [ ]  No | Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain the independent determination a physician who is (was) not otherwise participating in the clinical investigation. |
| [ ]  Yes [ ]  No | The investigator will submit (has submitted) the above written certification to the IRB within 5 working days after the use of the test article |
| [ ]  Yes [ ]  No | After the use of the test article a physician who is (was) not otherwise participating in the clinical investigation will certify (has certified) in writing within 5 working days after the use of the article that the above are true. |
| Emergency Use of a Device |
| 1. Exemption Criteria for Emergency Use of a Device (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a disease or condition that is (was) either:[ ]  Life-threatening meaning diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. [ ]  Severely debilitating meaning diseases or conditions that cause major irreversible morbidity. |
| [ ]  Yes [ ]  No | No generally acceptable alternative for treating the patient is (was) available. |
| [ ]  Yes [ ]  No | Because of the immediate need to use the device, there is no time to use existing procedures to get FDA approval for the use. |
| [ ]  Yes [ ]  No | The emergency use will be (was) reported to the IRB within 5 working days. |
| [ ]  Yes [ ]  No | Any subsequent use of the investigational product at the institution will have prospective IRB review and approval. |
| [ ]  Yes [ ]  No | The use is (was) **NOT** subject to DHHS regulation (See **WORKSHEET: Human Research Determination (HRP-309)**) |
| [ ]  Yes [ ]  No [ ]  N/A | The treating physician will obtain (has obtained) an independent assessment by an uninvolved physician. (**“N/A”** if there is insufficient time to obtain an independent assessment) |
| [ ]  Yes [ ]  No [ ]  N/A | If an IDE exists, the physician has (had) authorization from the sponsor. (**“N/A”** if there is no IDE) |
| [ ]  Yes [ ]  No [ ]  N/A | If an IDE does not exists, the physician will notify (has notified) FDA of the emergency use. (**“N/A”** if there is an IDE) |
| **One of Sections 6, 7, or 8 must be met** |
| 1. Consent Criteria (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | Informed consent will be (was) sought from the patient or the patient’s legally authorized representative. |
| [ ]  Yes [ ]  No | Informed consent will be (was) documented. |
| 1. Exception Criteria with Prospective Confirmation by an Independent Physician (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  Yes [ ]  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. |
| [ ]  Yes [ ]  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. |
| [ ]  Yes [ ]  No | Before the use of the test article an uninvolved physician will certify (has certified) in writing that the above items are (were) true. |
| 1. Exception Criteria with Retrospective Confirmation by an Independent Physician (All of the following are “Yes”)
 |
| [ ]  Yes [ ]  No | The patient is (was) confronted by a life-threatening situation necessitating the use of the test article. |
| [ ]  Yes [ ]  No | Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain consent from the patient’s legal representative. |
| [ ]  Yes [ ]  No | There is (was) no available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient. |
| [ ]  Yes [ ]  No | Before the use of the test article an uninvolved physician was unable to certify in writing that the above items are true. |
| [ ]  Yes [ ]  No | Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient. |
| [ ]  Yes [ ]  No | Time is (was) not sufficient to obtain the independent determination an uninvolved physician. |
| [ ]  Yes [ ]  No | The investigator will submit (has submitted) the above written certification to the IRB within 5 working days after the use of the test article |
| [ ]  Yes [ ]  No | After the use of the test article an uninvolved physician will certify (has certified) in writing within 5 working days after the use of the article that the above are true. |